

Data Management & Quality Control

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Role of Data Management (DM) team

- Assist study operations
- Produce data for data analysis
- Perform quality control

- Assist study operations
 - Screening & recruitment
 - Follow-up data collection
 - Endpoint adjudication

- Produce data for data analysis
 - Monitoring of study progress
 - Interim analyses
 - Final analyses

What is quality control?

- Ensure proper collection & flow of data
- Ensure completeness of data
- Ensure accuracy of data
- (Ensure proper analysis of data)

Tasks of DM team

- Design data collection instruments
- Design data collection methods
- Create relational data bases for data management
- Produce reports:
 - » Screening & recruitment
 - » Data collection & data quality
 - » Endpoints & endpoint adjudication
 - » Adherence to intervention protocol
- Data analysis
 - » Perform preliminary data checks & analysis
 - » Produce data sets for data analysis

When to start with DM & QC?

- Design phase of study
 - Adequate expertise
 - Adequate data collection & analysis plan
 - Adequate quality control procedures
 - Adequate resources for DM!!!

Data Collection Procedures

- Methods of data collection
 - Paper & pencil
 - » Less training required
 - » Lowest level of QC
 - Computer-assisted
 - » Much better QC
 - » May require staff training
 - » Lower cost (no data entry needed)
 - » More immediate data flow
 - Web-based/wireless technologies?

Quality Control Procedures

- Screening and recruitment
- Baseline and follow-up data collection
- Endpoint adjudication
- Intervention

Purpose of Skills Training Data

- Quality Control
- Measures of mechanisms
- External Validity
- Clinical purposes

QUALITY CONTROL

- Adherence to protocol
- Adherence of patients
- Acceptability of intervention
- Internal validity
 - ✓ across groups
 - ✓ across counselors

QUALITY CONTROL PROCEDURES

- Evaluation of participants' engagement and progress
- Evaluation of group leaders' skills in delivering the protocol
- Procedures for safety of high risk participants

Skills Training Data - Overview of Forms

- Process Log
- Leader Rating of Participant Progress
- Participant Questionnaire
- Support Giver Questionnaire

Process Log Form

Form to be completed at every session!!!

Process Log form

- Attendance of patients
- Reason for non-attendance
- Level of engagement of patients
- Completion of homework by patient

Skills Training Process Log

Participant's Initials in Pencil ____ (not for data entry)

PL01 Participant ID	____ _ -- ____ _ -- ____ _
PL02 Staff ID	____ _
PL03 Skills Training Group ID	____ _
PL04 Date of Contact	____ _ / ____ _ / 2 0 ____ _
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>PL05 Type of Contact</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <p><i>If PL05 = 4 – 5, skip to progress note</i></p> </div> </div> <div style="width: 50%;"> <p>Group – In Person = 1 Group – Speaker Phone = 2 Group – Conference Call = 3 Individual – In Person = 4 Individual – Phone = 5</p> </div> </div>	____ _
PL06 Session Number (01 – 18)	____ _
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>PL07 Attendance to Group?</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <p><i>If PL07 = 1 (present), skip to PL09</i></p> </div> </div> <div style="width: 50%;"> <p>Present = 1 Canceled = 2 No Show = 3</p> </div> </div>	____ _
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>PL08 Reason for absence</p> </div> <div style="width: 50%;"> <p>Illness = 1 Logistics = 2 Refused to attend = 3 Unable to Contact = 4</p> </div> </div>	____ _
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>PL09 Intervention Engagement Status</p> </div> <div style="width: 50%;"> <p>Fully Engaged = 1 Partially Engaged = 2 Chasing = 3 Dropped = 4 Deceased = 5</p> </div> </div>	____ _
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>PL10 Homework</p> </div> <div style="width: 50%;"> <p>Completed = 1 Partially Done = 2 Not Done = 3 Don't Know = 4</p> </div> </div>	____ _

Skills Training Data - I

Forms to be completed at session 1, 10, & 18

- Leader Rating Scale
 - ✓ Self-efficacy (SE) patient
 - ✓ Skill Acquisition Scale (SAS)
- Participant Questionnaire
- Support Giver Questionnaire